DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0386]

Talking With Stakeholders About FDA Modernization; Notice of Meetings and Teleconference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meetings and teleconference.

SUMMARY: The Food and Drug Administration (FDA) is announcing public meetings and an interactive satellite teleconference entitled ''Talking With Stakeholders About FDA Modernization.'' The purpose of the meeting is to discuss the agency's progress in implementing the FDA Modernization Act (FDAMA) and to seek additional input on specific FDAMA performance targets.

DATES: The meetings and teleconference will be held on April 28, 1999. The deadlines for speaker registration and attendance registration are April 9, 1999, and April 16, 1999, respectively. Stakeholders interested in being a member of the studio audience should indicate their interest by April 15, 1999. Comments may be submitted by May 14, 1999. For additional information regarding registration, the meetings, and teleconference, see Table 1 in section III of this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail ''FDADockets@bangate.fda.gov'', or via the FDA web site ''http://www.fda.gov''.

FOR FURTHER INFORMATION CONTACT: Carrie Smith Hanley, Office of External Affairs (HF–60), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3365, FAX: 301–594–0113, e-mail: ''chanley@oc.fda.gov''.

SUPPLEMENTARY INFORMATION:

NM-1

I. Background

Section 406(b) of FDAMA (21 U.S.C. 393(f) and (g)) requires the agency: To consult with its external stakeholders as it moves forward to modernize the agency; to develop a plan, based on input from stakeholders, for complying with the agency's obligations under the Federal Food, Drug, and Cosmetic Act (the act); and to periodically revisit the plan in consultation with stakeholders to make appropriate adjustments. As a culmination of these requirements, FDA will issue a performance report to Congress at the end of the 1999 calendar year.

A summary of the agency's responses to each obligation follows.

A. Consult With External Stakeholders

To respond to the first requirement of section 406(b) of FDAMA, the agency held a series of well attended public meetings last summer to obtain stakeholder views on how FDA can best meet its statutory obligations. Stakeholders offered a wealth of productive suggestions, many of which reflect their desire for greater involvement in FDA's work by contributing to the agency's future strategies and for receiving clear and timely information about the agency's processes and new regulated products.

B. Develop a Plan That Reflects Stakeholders Views

FDA listened carefully to its stakeholders and used their contributions to guide the development of a plan for complying with its obligations under FDAMA, as well as responding to the public's expectations. In the **Federal Register** of November 24, 1998 (63 FR 65000), the agency published the "FDA Plan for Statutory Compliance" (see FDA's web site, "http://www.fda.gov/oc/fdama/fdamapln"). This plan provides a broad, agency wide strategic framework and specific performance goals for the current fiscal year (1999) that will allow FDA to act on stakeholder recommendations as well as allow the agency to meet its statutory obligations. The strategic framework outlines six broad directions: Strengthening the science base, closely collaborating with stakeholders, establishing risk-based priorities, adopting a systems approach,

continuing to reengineer FDA processes, and capitalizing on information technology. The plan describes how the agency is already implementing many strategies in new and creative ways within each of these broad directions.

C. Periodically Revisit the Plan in Consultation with Stakeholders

FDA is now preparing to revisit the 406(b) plan as part of a formal consultation with its stakeholders on April 28, 1999. The agency would like to receive input from stakeholders on the elements of the plan that have been implemented thus far and obtain additional suggestions on how the agency can continue to improve its modernization efforts. FDA specifically wants input on how to: (1) Strengthen its science base and (2) improve its communication processes. To help focus the discussion at the April 28, 1999, meeting, FDA has designed five questions that address these two concerns. As stakeholders respond to these questions, it may be useful to review the ''FDA Plan for Statutory Compliance'' which outlines the agency's current and proposed activities in these two areas. FDA requests that stakeholders address the five questions below in their oral and/or written views:

1. Science based decisions are made throughout the life span of products from initial research, development and testing, through production, marketing, and consumption. These decisions require the best science to identify, evaluate, and balance product risks and benefits. It is crucial that FDA, in collaboration with product sponsors, develop a shared understanding of new science and technologies and their effect throughout a product's life span.

What actions do you propose the agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decisionmaking?

2. As the agency attempts to meet its public health responsibilities, the speed of discovery results in an avalanche of new information from government, academic, and industry scientists.

What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's lifecycle?

3. Most products in the American marketplace, especially medical ones, have two facets. On one side they benefit users and often improve lives. They are, however, rarely without risk, and their use can result in known and unknown side effects. Consumers must weigh benefits and risks before using these products, oftentimes with incomplete information.

What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decisionmaking?

4. The agency stated in the "FDA Plan for Statutory Compliance" that inflation has eroded real assets that can be applied to meet its public health mission while Congress has increased its responsibilities.

Because the agency must allocate its limited resources to achieve the greatest impact, what actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?

5. FDAMA requires the agency to continue to meet with stakeholders on key issues. Meetings have ranged from explaining the positions of the agency on particular issues to working with sponsors on product applications. Historically, these interactions have benefited both stakeholders, through better knowledge of FDA, and the agency, by leading to positive changes in its operations.

Because the agency wants to assure that its stakeholders are aware of and participate in its modernization activities, what additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?

II. Comments

Stakeholders are encouraged to submit their responses in advance of the April 28, 1999, meeting. Written comments should be identified with docket number 99N–0386 and submitted to the Dockets Management Branch (address above). In order to promote a variety of responses, stakeholders are encouraged to state a proposed action as a separate concise statement followed by a written explanation of its meaning.

III. Scheduled Meetings

Open public meetings with stakeholders will be held in several locations throughout the country. These meetings will provide down-link interactive viewing sites for the live satellite teleconference and also provide an opportunity for formal presentations to FDA's senior managers at the local meetings. The teleconference will feature Jane E. Henney, Commissioner of Food and Drugs, and Linda A. Suydam, Associate Commissioner for Strategic Management, who will be talking with stakeholders during the live satellite teleconference. These meetings are open to all stakeholders and will be co-hosted by FDA's field offices and centers, and they will focus on the specific product center listed in the first column of Table 1 of this document. The scheduled time of meetings, as listed in Table 1 of this document, includes the time devoted to the live satellite teleconference broadcast, as well as a period of time for presentations and/or discussion of the questions listed in section I.C of this document.

TABLE 1

Center/City Registration	Location/Address	Scheduled Time Of Meeting	Speaker Registration Contact	Attendance Contact
Center for Drug Evaluation and Research, Philadelphia, PA	Temple University, Main Campus, Ritter Hall, Kiva Auditorium, 130 Cecil B. Moore Ave., Philadelphia, PA	12:30 p.m. to 6 p.m. Eastern Time	Marcia Trenter, Phone: 301–827–1492, Fax: 301–827–3056, Email: Trenterm@cder.fda.gov	Anitra Brown-Reed, Phone: 215–597–4390 ext. 4202, Fax: 215–597–4660, Email: Abrown2@ora.fda.gov
Center for Biologics Evaluation and Research, Boston, MA	Boston University, School of Medicine, 715 Albany St., Boston, MA	9:30 a.m. to 3 p.m. Eastern Time	Lorrie Harrison, Phone: 301–827–5546, Fax: 301–827–3079, Email: Harrison@cber.fda.gov	Lorrie Harrison, Phone: 301–827–5546, Fax: 301–827–3079, Email: Harrison@cber.fda.gov
Center for Biologics Evaluation and Research, San Francisco, CA	South San Francisco Conference Ctr., 255 South Airport Blvd., South San Francisco, CA	9:30 a.m. to 3 p.m. Pacific Time	Lorrie Harrison, Phone: 301–827–5546, Fax: 301–827–3079, Email: Harrison@cber.fda.gov	Lorrie Harrison, Phone: 301–827–5546, Fax: 301–827–3079, Email: Harrison@cber.fda.gov
Center for Food Safety and Applied Nutrition, Chicago, IL	Ralph Metcalfe Federal Bldg., 77 West Jackson Blvd., Morrison Conference Room, Chicago, IL	12 Noon to 4:30 p.m. Central Time	Marquita Steadman, Phone: 301–827–6735, Fax: 301–480–5730, Email: msteadman@bangate.fda.gov	Kimberly Phillips, Phone: 312–353–7126 ext. 193, Fax: 312–886–3280, Email: Kphillip@ora.fda.gov
Center for Veterinary Medicine, Overland Park, KS	Johnson County Community College, Bldg. CE, rm. 211, 12345 College Blvd., (Kansas City, KS) (111th & Quivera), Overland Park, Kansas (Kansas City, KS)	11:30 a.m. to 5 p.m. Central Time	Linda Grassie, Phone: 301–827–6513, Fax: 301–594–1831, Email: Lgrassie@bangate.fda.gov	Linda Grassie, Phone: 301–827–6513, Fax: 301–594–1831, Email: Lgrassie@bangate.fda.gov
Center for Devices and Radiological Health, San Diego, CA	Scripps Research Institute, Shepherd Great Hall, Schaetzle Education Center, Scripps Memorial Hospital, 9890 Genesee Ave., La Jolla, CA, (San Diego)	9:45 a.m. to 4 p.m. Pacific Time	Ron Jans, Phone: 301–827–0048, Fax: 301–443–8810, Email: Rsj@cdrh.fda.gov	Ron Jans, Phone: 301–827–0048, Fax: 301–443–8810, Email: Rsj@cdrh.fda.gov
Office of Regulatory Affairs, Atlanta, GA	Food and Drug Administration, 60 Eighth St., N.E. Atlanta, GA	12 noon to 5 p.m. Eastern Time	Joann Pittman, Phone: 404–253–1272, Fax: 404–253–1202, Email: jpittman@ora.fda.gov	Joann Pittman, Phone: 404–253–1272, Fax: 404–253–1202, Email: jpittman@ora.fda.gov
FDA General, Washington, DC	United States Department of Agriculture, Jefferson Auditorium (West Wing), 14th and Independence Ave., SW., Washington, DC	12:30 p.m. to 5:30 p.m. Eastern Time	Mary Gross, Phone: 301–827–3364, Fax: 301–594–0113, Email: mgross@oc.fda.gov	Russell Campbell, Phone: 301–827–4413, Fax: 301–443–9767, Email: rcampbe2@oc.fda.gov

A separate FDAMA section on the FDA web site will provide current information about these public meetings. It is highly recommended that individuals who wish to participate at these public meetings plan to attend the entire session. Each public meeting will include an opportunity for an open comment session where attendees can express their views.

The interactive satellite teleconference is a C-Band broadcast with the following coordinates: satellite GE–2, 85 West, Transponder 3, frequency 3760 MHz Vertical. Test signal begins at 12 noon Eastern Time. The satellite teleconference will begin promptly at 1 p.m. Eastern Time and

end no later than 3:30 p.m. Eastern Time. Limited seating will be available for a live studio audience at the broadcast studio in Gaithersburg, MD. Individuals representing broad interest groups are invited to participate in the studio audience. A balanced representation of FDA stakeholders will be selected. Stakeholders who are interested in participating in the broadcast as a member of the studio audience should indicate their interest by April 15, 1999, to Carrie Smith Hanley, Office of External Affairs at the phone, fax or e-mail address listed in the section of this document entitled ''**For Further Information Contact**''.

IV. Registration and Requests for Oral Presentations

All participants should send registration information (including name, title, firm name, address, telephone and fax number) to the appropriate ''attendance registration'' contact person listed in section III of this document by April 16, 1999. If you need special accommodations due to a disability, please indicate such at the time of registration.

Participants who wish to make a formal oral presentation should register with the appropriate contact for ''speaker registration'' identified by meeting in section III of this document by April 9, 1999. Formal oral presentations will not be made at the studio. Stakeholders wishing to make presentations should make their wishes known to the appropriate individuals listed in section III of this document.

V. Transcripts

Transcripts of the meetings (from each site listed in section III of this document) may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville MD 20857, approximately 15 working

days after the meeting at a cost of 10 cents per page. The transcript of the meeting will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA web site ''http://www.fda.gov''.

Dated: March 17, 1999

William K. Hubbard
Acting Deputy Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Joyce Stong